0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *DSaRM@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On January 24 and 25, 2013, the committee will discuss the public health benefits and risks, including the potential for abuse, of drugs containing hydrocodone either combined with other analgesics or as an antitussive. The Department of Health and Human Services received a request from the Drug Enforcement Administration for a scientific and medical evaluation and scheduling recommendation for these products in response to continued reports of misuse, abuse, and addiction related to these products. The committee will also discuss the impact of rescheduling these hydrocodone products from Schedule III to Schedule II.

Background materials for the originally scheduled October 29–30, 2012, Drug Safety and Risk Management Advisory Committee meeting are currently available at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm307385.htm.* FDA intends to make background material available to the public no later than 2 business days before the January 24 and 25, 2013, Drug Safety and Risk Management Advisory Committee meeting at: *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. If FDA is unable to post background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and background material will be posted on FDA's Web site after the meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the docket (see the **ADDRESSES** section of this document) on or before January 9, 2013, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 10:15 a.m. on January 25, 2013. Those individuals interested in making formal oral presentations, including those who have previously requested time to speak at the originally scheduled October 29–30, 2012, Drug Safety and Risk Management Advisory Committee meeting, should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 3, 2013. Any individuals who requested time to speak at the originally scheduled October 29–30, 2012, Drug Safety and Risk Management Advisory Committee meeting, will need to follow the above instructions to request time to speak at the January 24–25, 2013, Drug Safety and Risk Management Advisory Committee meeting, as any previous requests to speak at the originally scheduled meeting do not convey to this new January 24–25, 2013, Drug Safety and Risk Management Advisory Committee meeting. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 4, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristina Toliver at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: *December 10, 2012.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30517 Filed 12–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1172]

Impact of Approved Drug Labeling on Chronic Opioid Therapy; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to obtain information, particularly scientific evidence, such as study data or peer-reviewed analyses, on issues pertaining to the use of opioid drugs in the treatment of chronic pain.

DATES: The public hearing will be held on February 7 and 8, 2013, from 9 a.m. to 4 p.m. Submit electronic or written requests to make oral presentations and comments by January 18, 2013. Electronic or written comments will be accepted after the hearing until April 8, 2013.

ADDRESSES: The public hearing will be held at the Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814, 301–897–9400, Fax 1–301–897–0192.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Transcripts of the hearing will be available for review at the Division of

Dockets Management and on the Internet at *http://www.regulations.gov* within 30 days of the meeting.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301–796–3416, FAX: 301–847–8752, *Elizabeth.Giaquinto@fda.hhs.gov;* or Mary Gross, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301–796–3519, FAX: 301–847–8752, *Mary.Gross@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Over the past several years, the role of opioid drugs in treating chronic pain has been an increasingly common subject of public discussion. FDA and other policymakers have been at the forefront of these debates, striving to find a balance between minimizing opioid drug abuse and misuse, while simultaneously enabling appropriate access to pain-relieving drugs. The July 9, 2012, approval of the Risk Evaluation Management Strategy for extended-release (ER) and long-acting (LA) opioid analgesics is a recent example of FDA's ongoing commitment to ensuring that the benefits of these types of opioid drugs continue to outweigh their risks.

While ER/LA opioid issues have been a particular focus of public health concern, discussions continue about the proper use of opioid drugs in general. Over the past several years, the Agency has received comments, petitions, and informal inquiries concerning the extent to which opioid drugs should be used in the treatment of pain. In particular, members of the public and the regulated community have debated the presence or absence of evidence showing the safety and efficacy of these drugs as pain relievers in the various populations for whom they are prescribed. Many have raised issues specific to particular opioids, such as those pertaining to drug product composition, specific abuse-deterrence properties, and biological action. Some have raised broader issues that impact the entire class of opioid drugs or a large subcategory thereof (e.g., ER/LA opioids), such as the propriety of controls on drug dosage and duration of administration or changes in indication and prescribing practices.

II. Purpose and Scope of the Public Hearing

In light of the ongoing interest in issues related to opioid use, FDA has decided to hold a public hearing to obtain information—particularly scientific evidence, such as study data or peer-reviewed analyses—from expert members of the public on the following questions:

A. Diagnosis and Understanding of Patient Pain

1. What methods do professionals use to accurately distinguish between different types of pain (e.g., cancer vs. non-cancer) and their respective etiologies?

2. What are the definitions of the terms ''mild,'' ''moderate,'' and ''severe'' when those terms are used to describe symptomatic conditions such as pain?

3. How do professionals accurately categorize a patient's pain as mild, moderate, or severe? For example, what tests or assessments do they use?

4. What methods should and do professionals use to accurately distinguish between short-term pain and chronic pain?

a. What are and should be the time periods that characterize short-term pain versus chronic pain?

b. What are and should be considered the clinical differences between short-term pain versus chronic pain?

c. What types of pain, if any, are presumed chronic versus presumed short term?

B. Understanding and Adhering to the Labels of Pain-Treating Products

1. How are the words ''indicated for the treatment of moderate to severe pain'' interpreted and used by practitioners when deciding what types of treatments (including opioids) are appropriate for treating patients with pain?

2. If the indication for opioid drugs were restricted to the treatment of severe pain only, how would such a change impact:

a. Prescribing practices?

b. Patient access to pain medication and patient pain control?

c. Abuse and misuse of opioid medicines?

3. If the pain threshold described in the indication (e.g., moderate, moderate to severe, severe pain) differed based on the pain's etiology, how would such an approach impact:

a. Prescribing practices?

b. Patient access to pain medication and patient pain control?

c. Abuse and misuse of opioid medicines?

C. Limiting Opioid Prescription and Use

1. Limits on exposure to opioid drugs.

a. What data, if any, exist that would support or oppose the establishment of a maximum daily dose for opioid drugs? FDA is interested in drug safety or efficacy data in particular.

b. What data, if any, exist that would support or oppose a difference in maximum daily dose for opioid drugs based on pain etiology (e.g., cancer vs. non-cancer pain)? FDA is interested in drug safety or efficacy data in particular.

c. What method(s), if any, should be used to establish a maximum daily dose of opioid drugs?

d. What effect(s), if any, would a maximum daily dose for opioid drugs have on the following:

i. Prescribing practices?

ii. Patient access to pain medication and patient pain control?

iii. Abuse and misuse of opioid medicines?

2. Limits on duration of use of opioid drugs.

a. What data, if any, exist that would support or oppose the establishment of a maximum duration of continuous treatment with opioid drugs? FDA is interested in drug safety or efficacy data in particular.

b. What data, if any, exist that would support or oppose a difference in maximum duration of continuous treatment with opioid drugs based on pain etiology (e.g., cancer vs. non-cancer pain)? FDA is interested in drug safety or efficacy data in particular.

c. What method(s), if any, should be used to establish a maximum duration of continuous treatment with opioid drugs?

d. What effect(s), if any, would a maximum duration of continuous treatment with opioid drugs have on the following:

i. Prescribing practices?

ii. Patient access to pain medication and patient pain control?

iii. Abuse and misuse of opioid medicines?

III. Attendance at and/or Participation in the Public Hearing

If you wish to attend the hearing or make an oral presentation during the hearing, you must register by submitting either an electronic request (see the Web address listed at the end of this paragraph) or written request (see **FOR FURTHER INFORMATION CONTACT**) by close of business on January 18, 2013. You must provide your name, title, business affiliation (if applicable), address, and type of organization you represent (e.g., industry, consumer organization), and a brief summary of your presentation, if applicable (including the discussion topic(s) that will be addressed), to *https://www.surveymonkey.com/s/2R5QWZP* by January 18, 2013.

FDA will notify registered presenters of their scheduled presentation times. Persons registered to make an oral presentation should check in before the

hearing and are encouraged to arrive early to ensure the designated order of presentation times. We will try to accommodate all persons who wish to present; however, the duration of each speaker's testimony may be limited by time constraints. An agenda of the meeting and other background material will be made available 5 days before the meeting at *http://www.fda.gov/Drugs/NewsEvents/ucm326450.htm.*

Questions about the meeting may also be also submitted to *IssuesWithOpioids@fda.hhs.gov* prior to the February 7 and February 8, 2013, meeting dates.

The hearing is free and seating will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the numbers of participants from individual organizations as well as total number of attendees based on space limitations. Registrants will receive confirmation once they have been accepted to attend the hearing. For those who cannot attend in person, information regarding viewing a live Web cast of the public hearing will be located at: *http://www.fda.gov/Drugs/NewsEvents/ucm326450.htm.*

If you need special accommodations due to a disability, contact Elizabeth Giaquinto or Mary Gross (see **FOR FURTHER INFORMATION CONTACT**).

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

The hearing will be transcribed as stipulated in § 15.30(b). A transcript will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.regulations.gov* within 30 days of the meeting. A transcript will also be available in either hard copy or on CD–ROM after submission of a Freedom of Information request. Submit written requests to the Division of Freedom of Information (ELEM–1029), Office of Management Programs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments for consideration by April 8, 2013. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments so that they identify the specific questions to which they refer. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: *December 13, 2012.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30516 Filed 12–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 USC, as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; N43DA13–4417: Video Gaming Targeting Relapse Prevention in Youth with Substance Use Disorders.

Date: January 9, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Nadine Rogers, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4229, MSC 9550, Bethesda, MD 20892–9550, 301–402–2105, *rogersn2@nida.nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Profile Screening and Predictive Toxicology (8909).

Date: February 12, 2013.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 435–1439, *lf33c.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: December 13, 2012.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–30453 Filed 12–18–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials,